



## GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF  
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Docket No. 98N-0359; Program Priorities in the Center for Food  
Safety and Applied Nutrition, Fiscal Year 2003; Request for  
Comment; 67 Fed. Reg. 42272 (June 21, 2002)**

The Grocery Manufacturers of America, Inc. (GMA) appreciates this opportunity to offer comments concerning program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year 2003. GMA commends CFSAN's ongoing commitment to transparency and stakeholder input as it focuses its workplan on those core areas most likely to yield the greatest benefits for consumers.

GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than \$450 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues.

The following comments relate to CFSAN's program priorities for FY 2003. For ease of reference, topics are addressed in the order in which they appear in the FY 2002 workplan.

### **I. PRIORITY AREA I: ASSURING FOOD SAFETY AND SECURITY**

#### General

GMA recommends that FDA retain ongoing priority items in the areas of food security and food safety. GMA understands that, as a general rule, CFSAN intends to promote items currently identified on the "B\*" list to the "A" list in FY 2003, including those "A" list goals that were temporarily moved to the "B\*" list in July 2002. More specific comments on areas of particular importance follow.

#### Priority Item I.1; Food Security: General

GMA supports the continued positioning of food security as CFSAN's primary priority area in FY 2003. In this regard, continued "A" list designations are indicated for each of the new regulations required to implement the Public Health Security and Bioterrorism

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Preparedness and Response Act of 2002 (Pub. L. No. 107-188). “A” list designations are also warranted for activities relating to food security research needs.

The FY 2002 workplan, as modified in July 2002, indicates that the agency intends to conduct increased sample analyses on products with “suspect histories.” GMA appreciates that increased surveillance is an important and ongoing component of the agency’s food security work, and that the FDA Office of Regulatory Affairs (ORA) has hired over 600 new food safety investigators and laboratory personnel for this purpose. The agency is prudent to focus enforcement resources on products that may reasonably be considered to pose a greater risk relative to other products. To ensure that safe and wholesome products are not unfairly or disproportionately targeted, however, the agency is urged to use objective, risk-based criteria to identify those products deemed to warrant increased oversight. The agency is also urged to consider not only the nature of the product or product category but also company history. Through a careful evaluation of relative risk that takes into account all relevant factors, the agency may safeguard the food supply while ensuring that the free flow of goods is not impeded unnecessarily.

#### Priority Item I.7: Listeria

In the current fiscal year, the agency has prioritized as an “A” list item the collection of additional exposure data regarding *Listeria monocytogenes* (LM) in select foods; revision of the draft LM risk assessment is presently categorized as an “B\*” priority. For FY 2003, the agency is urged to designate the draft LM risk assessment as an “A” list item that is slated for final publication prior to September 30, 2003.

## **II. PRIORITY AREA II: ASSURING FOOD AND COSMETIC SAFETY: SPECIFIC PROGRAM AREAS**

### General

GMA recommends that FDA retain ongoing priority items in the specific food-related program areas identified in priority area II—food and color additives and ingredients, nutrition, health claims, and labeling, and dietary supplements. GMA understands that CFSAN intends to promote items currently identified on the “B\*” list to the “A” list in FY 2003, including those “A” list goals that were temporarily moved to the “B\*” list in July 2002.

#### Priority Item II.1: Premarket Review of Food and Color Additives and Food Ingredients

GMA requests that FDA retain as a priority item 2.1.3, which pertains to the adoption into agency regulations of specifications in the most recent edition of the Food Chemicals Codex (FCC). By using the current FCC specifications, CFSAN will ensure that the most recent information about food additives and GRAS substances is incorporated in its regulations. Such actions also will eliminate the confusion of whether manufacturers should adopt the specifications in the existing FCC monographs or the specifications cross-referenced in the food additive and GRAS regulations. To ensure that its regulations are updated in a timely fashion, CFSAN is urged to establish procedures for the routine adoption of FCC standards and specifications as they are issued.

GMA requests that FDA/CFSAN review and modernize the Standards of Identity as a priority "A" for 2003.

#### Priority Item II.2: Nutrition, Health Claims, and Labeling

CFSAN is urged to designate as specific "A" list items implementation of the pasteurization and irradiation provisions of the Farm Security and Rural Investment Act of 2002 (the "Farm Bill") (Pub. L. No. 107-171). GMA understands these provisions to (1) establish new criteria for use of the term "pasteurization" in labeling, (2) require the Center to publish a proposed and final rule to revise, as appropriate, the current regulation governing the labeling of foods that have been treated with irradiation, and (3) establish certain conditions for the submission of petitions regarding the labeling of particular irradiated foods pending completion of the required rulemaking. Implementation of these items is recommended for inclusion on the Center's "A" or "B\*" lists.

GMA also recommends for "A" list inclusion CFSAN participation in the agency's review and consideration of First Amendment issues, as announced in the May 16, 2002 *Federal Register*. 67 Fed. Reg. 34942. As FDA has recognized, recent case law has emphasized the need for regulatory agencies to avoid unnecessary restrictions on speech. *Id.* The agency sought public comment to ensure that its regulations, guidances, policies, and practices comply with governing First Amendment case law. In light of these developments, the following items are requested for addition to the CFSAN "A" list:

- Participation in the FDA review and consideration of First Amendment issues.
- Publication of a final rule providing for more flexibility in the use of health/nutrient content claims, which is identified as a "B" list item in the FY 2002 workplan (item 2.2.4).
- Review of the agency's strategy to implement *Pearson v. Shalala*, with specific consideration of the applicability of the general First Amendment concepts set forth in the decision to conventional foods.

### **III. PRIORITY AREA III: ASSURING FOOD SAFETY: CROSSCUTTING AREAS**

#### General

GMA supports continued emphasis on FY 2002 items that have not been completed in the crosscutting areas identified in priority area III. GMA understands that CFSAN intends to promote items currently identified on the "B\*" list to the "A" list in FY 2003.

#### Priority Item III.3: International

GMA is committed to meaningful liberalization of international trade in food and beverages. Such liberalization is critically dependent upon scientifically sound applications of sanitary and phytosanitary (SPS) measures and elimination of technical barriers to trade. To ensure the development of appropriate scientific measures on a global basis, GMA supports "A"

list designations for CFSAN work in Codex, JECFA, WHO food safety planning programs, and NAFTA technical working groups. CFSAN is urged to continue to assume a leadership role, as appropriate, in these groups.

Priority Item III.4: Food Biotechnology

CFSAN is urged to finalize its biotechnology mandatory premarket notification proposal in FY 2003. In addition, to ensure that consumers are not misled regarding the use of modern biotechnology in the production of food, GMA urges CFSAN to designate as an "A" list priority issuance of final labeling guidance on voluntary label statements indicating whether a food has or has not been developed using modern biotechnology.

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GMA is committed to enhancing the safety and quality of America's food supply through cooperative and science-based regulation. GMA looks forward to working with the Agency in FY 2003 and beyond and would be pleased to discuss with CFSAN any of the points made in these comments.

A handwritten signature in black ink, appearing to read "James H. Skiles", is written over a horizontal line.

James H. Skiles

Vice President and General Counsel